



BILLING CODE 6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA-HQ-OPP-2017-0474; FRL-9981-27]**

#### **Aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt; Exemption from the Requirement of a Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt (CAS Reg. No. 144538-83-0) when used as an inert ingredient in antimicrobial pesticide products for which, when ready for use, the end-use concentration does not exceed 5,000 parts per million (ppm) of aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt. Lanxess Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt, when used in accordance with the terms of the exemption.

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2017-0474, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDfRNotices@epa.gov](mailto:RDfRNotices@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2017-0474 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of*

*publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2017-0474, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Petition for Exemption**

In the **Federal Register** of December 15, 2017 (82 FR 59604) (FRL-9970-50), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11063) by Lanxess Corporation, 111 RIDC Park West Drive, Pittsburgh, PA 15275. The petition requested that 40 CFR 180.940(a) be amended by establishing an exemption from the requirement of a tolerance for residues of aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt (CAS Reg. No. 144538-83-0) when used as an inert ingredient as a chelating agent in antimicrobial pesticide formulations (food-contact surface sanitizing solutions). That document referenced a summary of the petition prepared by Lanxess Corporation, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no relevant comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has limited the maximum end-use concentration, when ready for use, of aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt not to exceed 5,000 ppm in antimicrobial formulations. The reason for this change is explained in Unit V.B. below.

### **III. Inert Ingredient Definition**

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers;

microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

#### **IV. Aggregate Risk Assessment and Determination of Safety**

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction

with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

In a mammalian metabolism study, only 37% of the administered dose was systematically available (34.7% urine and 2.2% tissues and carcass), and most of that was from second phase absorption. Primary radioactivity recovered after 72 hours was from urine and feces, with 68.7 % of the radioactive dose being excreted in the feces and 34.7% of the radioactive dose being excreted in the urine.

Aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt exhibits low levels of acute toxicity. An acute study in rats showed an oral Lethal Dose (LD)<sub>50</sub> >2,000 milligram/kilogram (mg/kg). The dermal LD<sub>50</sub> in rats was > 2,000 mg/kg. It was not shown to be a skin or eye irritant or dermal sensitizer. There are no inhalation studies available.

Two 28-day studies (drinking water and gavage) were conducted with Wistar rats using aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt. There were no toxicologically related adverse effects seen at dosed up to and including 1,750 mg/kg/day or 1,000 mg/kg/day, respectively.

Aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt was administered to rats (drinking water and gavage) in two 90-day toxicity studies. In both studies effects were seen in the kidneys and urinary bladder. In the drinking water study, the most sensitive endpoint (i.e., moderate diffuse transitional cell hyperplasia in the urinary bladder) was seen in both the main group and satellite groups (recovery phase) males exposed to 300 mg/kg/day and greater. Therefore, the NOAEL was 100 mg/kg/day and the LOAEL was 300 mg/kg/day based on this diffuse transitional cell hyperplasia in the urinary bladder.



In the 90-day gavage study, again effects were seen in the kidney and urinary bladder, this time the most sensitive endpoint was based on the effects seen at 1,000 mg/kg/day: hyperplasia of the transitional cell epithelium of the bladder, basophilic cortical tubules in the kidneys, and other urinary changes (e.g., increased urinary pH, as well as some changes observed in clinical pathology (increased blood urea concentrations in males; slightly lower blood concentrations of potassium and chloride)). The NOAEL for this study was 200 mg/kg/day and the LOAEL was 1,000 mg/kg/day based on hyperplasia of the transitional cell epithelium of the bladder, basophilic cortical tubules in the kidneys, and other urinary changes.

In a developmental toxicity study, groups of inseminated female rats were treated with aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt daily by oral gavage from day 6 to day 19 post coitum in doses of 0, 100, 300, or 1,000 mg/kg/day. Decreased food consumption and body weight gain were seen in treated females at 1,000 mg/kg/day. No developmental effects were observed in this study at doses up to and including 1,000 mg/kg/day.

Aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt was administered to groups of rats in drinking water in a one generation reproductive toxicity study. Reproduction parameters were not affected at dose levels up to 16,000 ppm (~2081 mg/kg/day). The body weight development of F<sub>1</sub> pups was decreased at 16,000 ppm. The concentration of 4,000 ppm (~411 mg/kg/day) was established as the NOAEL for the parent animals based on macroscopic and microscopic changes in the kidneys at the LOAEL of 16,000 ppm. The reproductive NOAEL was 16,000 ppm. The offspring

toxicity NOAEL was 4,000 ppm based on decreased body weight development of F<sub>1</sub> pups seen at 16,000 ppm.

Aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt was administered in drinking water to Wistar rats for up to two years, groups of inseminated female rats were treated daily by oral gavage from day 6 to day 19 post coitum in doses of 0, 100, 300, or 1,000 mg/kg/day. Decreased food consumption and body weight gain were seen in treated females at 1,000 mg/kg/day. No developmental effects were observed in this study at doses up to and including 1,000 mg/kg/day.

Body weight development of males treated at 1,000 mg/kg/day was slightly decreased but statistically significant. Water consumption was increased in all treated groups; however, at 100 mg/kg/day the differences were slight. Increased urine excretion and changed feces consistency (soft) observed at clinical observation of the animals are regarded to be secondary to the increased water intake. The most consistent finding in the urinalysis was an increase of the pH of the urine at 1,000 mg/kg/day in both sexes at most all time points.

At microscopy of urinary sediment, erythrocytes were more frequently observed at 1,000 mg/kg/day mainly in males at the first three of four time points. At necropsy, kidneys weights were increased starting at 300 mg/kg/day in females and 1,000 mg/kg/day in males. Furthermore, the kidneys of females treated for two years showed discoloration and increased surface changes starting at 300 mg/kg/day. Histopathological evaluation of the kidneys revealed increased incidence of small mineralizations in the renal parenchyma in males at 1,000 mg/kg/day, mineralized concretions in the renal

pelvis in both sexes starting at 300 mg/kg/day, and increased severity of chronic progressive nephropathy (CPN) in females starting at 300 mg/kg/day. These findings likely indicate a mineral imbalance/influence on calcium homeostasis, leading to an increased incidence of parenchymal and pelvic mineralizations. The NOAEL for this study was 100 mg/kg/day with a LOAEL of 300 mg/kg/day based on increased water consumption, increased severity of CPN, and macroscopic and microscopic changes in the kidney. Aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt was not carcinogenic in this study.

There is no evidence that oral exposure to aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt suppresses or otherwise harms immune function in mammalian systems. No signs of neurotoxicity were reported in acute or repeat-dose oral studies. There were also no signs of carcinogenicity in the database including the 2-year feeding study. Similarly, all tests for genotoxicity, mutagenicity, and clastogenicity were negative.

#### B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in

conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

*<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.*

The point of departure for this risk assessment for all durations (except acute) and routes of exposure is from the two-year drinking water toxicity study in rats. The NOAEL is 100 mg/kg/day and the LOAEL is 300 mg/kg/day based on increased water consumption, CPN, macroscopic and microscopic changes in the kidney. Similar effects were seen in a 90-day drinking water study and the same NOAEL and LOAEL were recorded. A 100-fold uncertainty factor was used (10X interspecies extrapolation, 10X for intraspecies variability, and 1X Food Quality Protection Act Safety Factor (FQPA SF)). The FQPA SF is reduced to 1X because the reproductive and developmental toxicity database is complete and there is no evidence of increased risk to infants and children. See Section VII below for more information on the FQPA SF.

Because no acute effect was attributed to aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt, an acute assessment was not conducted. When the 100X uncertainty or safety factor is applied, the cPAD is 1 mg/kg/day. The residential and aggregate LOC is for MOEs that are less than 100 and is based on 10X interspecies extrapolation, 10X for

intraspecies variability and 1X FQPA factor. In the absence of dermal absorption data, dermal absorption is estimated to be 100%

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt in food as follows:

To assess dietary exposure, the Agency calculated the Daily Dietary Dose (DDD) and the Estimated Daily Intake (EDI) using US Food and Drug Administration (FDA) Food Contact Surface Sanitizing Solution Dietary Exposure Assessment Model. EPA's assessment used FDA's default assumptions for the amount of residual solution or quantity of solution remaining on the treated surface without rinsing with potable water (1 mg/cm<sup>2</sup>); surface area of the treated surface which comes into contact with food (4,000 cm<sup>2</sup>); and the pesticide migration fraction (100%). EPA used an application rate of aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt of 5,000 ppm, which was provided by the submitter. EPA also derived exposure amounts for population subgroups by accounting for body weights and adjusting for relative food consumption using data from the National Health and Nutrition Examination Survey (NHANES) (specifically the 2003-2008 survey data).

The use of aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt as a bleaching stabilizer in the manufacture of paper and paperboard has been approved by the FDA as

an indirect food additive in food-contact paper and paperboard at levels not to exceed 0.18 percent by weight of the dry pulp. The migration of aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt from food contact paper and paperboard into food, and subsequent dietary exposure has been included in the overall dietary exposure.

2. *Dietary exposure from drinking water.* The proposed inert ingredient will be used in low concentrations in food-contact antimicrobial pesticide products (food-contact surface sanitizing solutions), which will be used indoors. This use pattern would not be expected to result in measurable levels in surface waters or drinking water. Therefore, for the purpose of the screening-level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt, drinking water values were considered negligible and are not expected to contribute to the overall dose.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). Aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt will be used in residential settings in antimicrobial pesticide products applied to food-contact surfaces. As such, dermal exposure to aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt is possible; therefore, a residential exposure assessment was completed. The Agency conducted a conservative assessment of potential residential exposure by assessing aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt in antimicrobial pesticide formulations used for hard-surface disinfection in and around the home. The Agency's residential exposure

includes dermal exposures only as based on the lack of volatility of aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt, inhalation exposure is not expected to occur.

The wiping scenario was utilized for this assessment. In this scenario, residential handlers (i.e., applicators) are assumed to be wearing shorts and short-sleeve shirts, shoes, and socks (and no gloves). Residential post-application exposures were not assessed for this scenario as such exposures would be expected to be negligible. Reliable exposure data from non-pesticidal uses such as use in cosmetics was not available.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.” EPA has not found aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt to share a common mechanism of toxicity with any other substances, and aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

*D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* No effects on infants and children were seen in either a reproductive or developmental study in the absence of maternal effects at the limit dose of 1,000 mg/kg/day. A reproductive study showed no effect on reproductive parameters or fertility at doses > 2,000 mg/kg/day (16,000 ppm). Decreased body weight gain was seen in pups at 16,000 ppm. This effect was observed in the presence of maternal toxicity indicating that there is no increase in susceptibility to offspring.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt is complete.



ii. There is no indication that aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt results in increased susceptibility in *in utero* rats in the prenatal developmental studies or in young rats in the reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. In order to account for all potential exposure, a conservative exposure assessment was performed assuming a 100% transfer coefficient and 100% dermal absorption. This model assumes a worst case scenario of no gloves, shorts and short sleeved shirt. Based on these conservative assumptions, EPA believes that using this model will not underestimate the exposure and risk from aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt as an inert ingredient in antimicrobial pesticide products.

#### *E. Aggregate Risks and Determination of Safety*

*Determination of safety section.* EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt from food will utilize 72% of the cPAD for children (1-2 year old), the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt may be used as an inert ingredient in pesticide products that are registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposure to aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt.

Using the exposure assumptions described above for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 200. Because EPA's level of concern for aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt is a MOE of 100 or below, this MOE is not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water

(considered to be a background exposure level). Aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt may be used as an inert ingredient in pesticide products that are registered for uses that could result in intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposure to aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt.

Using the exposure assumptions described above for intermediate-term exposures, EPA has concluded the combined intermediate-term food, water, and residential exposures result in aggregate MOEs of 200. Because EPA's level of concern for aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt is a MOE of 100 or below, this MOE is not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in rodent carcinogenicity studies, aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt residues.

## **V. Other Considerations**

### *A. Analytical Enforcement Methodology*

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt in or on any food commodities. EPA is establishing limitations on the amount of aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt that may be used in pesticide formulations applied to semi-permanent or permanent food-contact surfaces. These limitations will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), 7 U.S.C. 136 et seq. EPA will not register any pesticide formulation for use in antimicrobial pesticide products for sale or distribution that exceeds 5,000 ppm of aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt in the final formulation unless additional data are submitted that demonstrate a higher concentration would be safe.

*B. Revisions to Petitioned for Tolerances*

Although the petition did not specify a limitation on concentration of this inert ingredient in end-use antimicrobial pesticide formulations, the Agency is establishing this exemption with the limitation of 5,000 ppm in pesticide formulations. Based upon an evaluation of the data included in the petition, unlimited use resulted in risks of concern; therefore, EPA is establishing a limitation in formulation when ready for use, (i.e., the end-use concentration is not to exceed 5,000 ppm) in order to support the safety finding for this tolerance exemption. This limitation is based on the Agency’s risk assessment which can be found at <http://www.regulations.gov> in document *IN-11063; Aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt: Human Health Risk and Ecological Effects Assessment of a Food Use Pesticide Inert Ingredient* in docket ID number EPA-HQ-OPP-2017-0474.

## **VI. Conclusions**

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.940(a) for aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt (CAS Reg. No. 144538-83-0) when used as an inert ingredient (as a chelating agent) in antimicrobial pesticide formulations (food-contact surface sanitizing solutions) applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at a maximum of 5,000 parts per million (ppm) in final formulation.

## **VII. Statutory and Executive Order Reviews**

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special

considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

#### **VIII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 15, 2018.

Michael L. Goodis,

*Director, Registration Division, Office of Pesticide Program.*



Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In §180.940 in paragraph (a), add alphabetically the inert ingredient “Aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt” to the table to read as follows:

**§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).**

\* \* \* \* \*

(a) \* \* \*

Pesticide Chemical	CAS Reg. No.	Limits
* * *	*	* * *
Aspartic acid, N-(1,2-dicarboxyethyl)-, tetrasodium salt	144538-83-0	When ready for use, the end-use concentration is not to exceed 5000 ppm
* * *	*	* * *

\* \* \* \* \*